SEP - 9 2003

K032179

510(k) SUMMARY

Submitter:

Parkell, Inc.
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Contact:

Nelson J. Gendusa, DDS
Director of Research
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155 Schmitt Blvd.
Box 376
Farmingdale, NY 11735

Submission Date:

15 April 2003

Trade Name:

Currently Not Available

Common Name:

Resin Primer

Classification Name:

Material, Tooth Shade, Resin

Equivalence:

Special Bond and Special Bond II

Description/Intended Use:

A light-cured, resin-based primer that is used to enhance the bond of old to new resin-based materials. The material is indicated for use on the intaglio of indirect composite restorations. It can be used to refresh the worn but otherwise intact surfaces of composite resin restorations.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 9 2003

Nelson J. Gendusa, DDS
Director of Research
Parkell, Incorporated
155 Schmitt Boulevard, Box 376
Farmingdale, New York 11735

Re: K032179
Trade/Device Name: Comp.E
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: II
Product Codes: KLE and EBI
Dated: July 09, 2003
Received: July 14, 2003

Dear Dr. Gendusa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K032179

Device Name: Comp. E

Indications for Use: For use in repairing, adding to, or otherwise modifying the surface of resins . Especially useful for enhancing co-polymerization between an old and a new composite resin when the former requires refreshing or repair in order to extend its clinical life. May also be used as the primer of intaglio surfaces of indirect, resin-based restorations to enhance the bond of these with resin-based luting materials. This agent is also useful for bond enhancement of highly cross-linked denture teeth, acrylic or composite, to denture base resins. This material will improve the union between resin surfaces in a myriad of situations, both intra- and exta-orally.

Kai Mulay for MSR

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K032179